EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: AMERICAN MEDICAL SYSTEMS, INC.
PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION

Case No. 2:12-cv-2325

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 24
(Plaintiffs' Motion to Compel Production
of Documents Outside the United States, ECF No. 279)

In this multi-district litigation ("MDL") concerning mesh products used to repair pelvic organ prolapse and stress urinary incontinence, the plaintiffs have moved the court to compel American Medical Systems, Inc. ("AMS") to produce into the MDL depository documents and things in the care, custody and control of AMS which are outside the United States (so-called "OUS" materials). (ECF No. 279.) AMS has responded in opposition (ECF No. 304), and the plaintiffs have filed a reply (ECF No. 309).

Rule 34 of the Federal Rules of Civil Procedure is not limited to documents and things which are stored in the United States. In fact, it is well-settled that foreign companies related to American domestic companies are subject to production of their relevant documents. *Societe Internationale Pour Participations Industriales Et Commerciales, SA v. Rogers*, 357 U.S. 197, 205 (1958) (failure to produce records because of fear of punishment under the laws of its sovereign would undermine congressional policies and invite efforts to place ownership of American assets in persons or firms whose sovereign assures secrecy of records); *Tequila Centinela, S.A. de C.V. v. Bacardi & Co.*, 242 F.R.D. 1, 12 (D.D.C. 2007) ("the Court is aware of no rule which precludes discovery of ordinarily discoverable material, solely on the basis that it calls for information outside of the United States or involves facts or activities outside of the United States"). AMS does not dispute that its OUS documents are within its care, custody and control, and it does not seriously argue that its OUS documents are not relevant. The discovery requests seek information about important topics, including when AMS knew or should have known about the frequency and severity of complications associated with their products, what AMS did to warn patients and physicians of those complications, and what AMS did to market their products in light of its knowledge of those complications. Accordingly, the court will not linger on whether Rule 34 covers the documents, and will address AMS's arguments in opposition to the Motion to Compel.

AMS claims the motion is premature.

AMS asserts that "there is no discovery pending in the MDL" and that the plaintiffs "have not established any practical need for AMS to search for, review, and produce documents that may happen to be located in the many countries in which AMS conducts business." (ECF No. 304, at 2.) It suggests that the plaintiffs' demand for OUS materials is a form of discovery abuse. (*Id.*)

AMS's position that "there is no discovery pending" is puzzling. Pretrial Order # 10 (ECF No. 188) lifted the stay on discovery. The plaintiffs served their "First Requests for Production of Documents, etc." (ECF No. 279-7) on June 15, 2012. Several protocols and stipulations have been filed relating to the production of documents and electronically stored information, and many documents have been produced to the depository. The attorneys met and conferred on the topic of OUS materials; when AMS steadfastly refused to produce them, counsel negotiated the briefing schedule on this Motion.

Later in its response, AMS asserts that "[t]he only formal requests for foreign materials requested by Plaintiffs are the Delaware RFP Nos. 7-9-11, 15, 17, 26, and 61 and MDL RFP Nos. 15, 17 and 32, which seek foreign regulatory, safety and labeling documents." (*Id.*, at 13.) This statement suggests that AMS is taking the position that it need not produce documents in foreign countries unless the plaintiffs specifically requested documents provided to a foreign government. This is belied by AMS's blanket objection to all discovery requests by the plaintiffs as to OUS materials. To be clear, AMS conducts business in the United States and in sixty countries; its documents are in the United States and in sixty countries; its relevant and non-privileged documents, wherever they are located, are in AMS's care, custody and control and are discoverable. The court expects them to be produced, without excessive duplication or unnecessary delay.

AMS's assertion that the plaintiffs should show that they "need" documents in other countries is similarly odd. AMS is the party whose burden it is to produce or make available for inspection and copying its documents which are responsive to discovery requests and otherwise discoverable.

AMS claims the plaintiffs' discovery requests are unreasonable.

AMS contends that "the burden and expense to AMS of collecting and producing the foreign discovery substantially outweighs the limited benefit of such discovery to the Plaintiffs, given that the foreign discovery bears no relevance to these U.S. plaintiffs and that such discovery is duplicative of what is available (and will be produced) in the U.S." (ECF No. 304, at 7.)

> The AMS pelvic repair devices at issue in their lawsuits were designed and manufactured in the United States by a US company, and all decisions relating to their safety, warnings, and marketing were made within the United States. Plaintiffs do not contend that any of them obtained an AMS device from a foreign country. Plaintiffs do not contend that any of Plaintiffs' physicians were influenced to use AMS devices due to any OUS marketing or warnings, or that they were trained to use these devices overseas. Plaintiffs do not contend that AMS's foreign regulatory communications have any bearing on AMS's compliance with FDA regulations or any state law. Nothing in the Master Complaint mentions or involves OUS activity. As such, the foreign discovery is unimportant to the resolution of the issues in this litigation.

(*Id.*)

The court finds that the plaintiffs' discovery requests for OUS materials are reasonable. The human body's reaction to implantation of pelvic repair products does not depend upon the patient's nationality, race or native language; adverse reports from France, India, South Africa, Brazil, or Australia are as relevant as those from the United States. Medical research on the efficacy of such products is relevant whether it is written in Greek or English. AMS's pelvic repair products were manufactured in the United States and Ireland, but they have been, and are, implanted in women worldwide (30% are used outside the United States). The court instructs AMS not to burden the depository with materials which are duplicates of documents kept in the United States and already produced to the depository.

AMS claims the plaintiffs' discovery requests are burdensome and wasteful.

AMS does business in sixty countries. It argues that "searching for, gathering and reviewing documents from around the world would take an enormous amount of time and resources." (*Id.*, at 8.) AMS notes that there are foreign legal and data privacy hurdles, conflicting laws, and the expense of hiring translators and consultants. (*Id.*, at 9-10.) It states in a conclusory fashion that the burden of such production outweighs its potential benefit.

The court notes that AMS was and is willing to undertake the expense of doing business in sixty countries for the purpose of selling its products; responding to litigation is an expected part of doing that business. AMS handles all "significant safety issues" in Minnesota, no matter where they arise; the court is unaware whether AMS considers this MDL and the plaintiffs' complaints to be a "significant safety issue;" but if so, it should be an easy matter to produce documents relating to worldwide complaints which are similar to those made by the plaintiffs. AMS claims that "[n]o foreign employees were involved in decision-making regarding safety, labeling, warnings, regulatory compliance, clinical studies, physician training, and marketing for the pelvic mesh devices *sold in the United States*." (*Id.*, at 3.) (Emphasis supplied.) AMS's statement ignores the fact that its decision-making regarding safety, labeling, warnings, regulatory compliance, clinical studies, physician training and marketing in foreign countries constitutes corporate knowledge of the risks and benefits of its products, wherever they are implanted. The plaintiffs are entitled to discover the extent of AMS's knowledge.

AMS expects that copies or originals of "virtually all relevant and responsive foreign-originated documents, as well as documents exchanged between AMS and a foreign affiliate, *that relate to the AMS pelvic mesh devices sold in the United States*, if any, are kept in AMS's ordinary course of business in the United States and will be located within AMS's custody and control in the United States." (*Id.*, at 3-4.) (Emphasis supplied.) The difficulty with this position is that the plaintiffs are entitled to review foreign-originated documents that relate to the AMS pelvic mesh devices sold in foreign countries. Even if a significant percentage of the AMS pelvic mesh products sold in foreign countries resulted in adverse medical events, AMS would argue that it has no obligation to disclose those documents because the devices were not sold in the United States. The court cannot accept such a position. Product liability litigation is a modern cost of doing business in any nation, and AMS has not persuaded this judicial officer that it should be relieved of that cost.

The burden and expense of producing email is somewhat alleviated by AMS's practice of storing its email on servers located in the United States and the Netherlands. The court expects counsel for the plaintiffs to cooperate with AMS in identifying a limited number of foreign employees whose computers and email must be searched. Privacy of foreign patients should be protected, and the parties should consider whether patient identifiers and irrelevant material can be completely redacted.

AMS claims the plaintiffs should bear the costs of discovery of OUS materials.

AMS invokes Rule 26(b)(2)(B)'s provision which authorizes a court, in its discretion, to consider limitations on discovery of electronically stored information if the producing party establishes that it needs protection from "undue burden or expense." AMS, a company which does billions of dollars in sales, has failed to show that it needs protection from undue burden and expense.

It is hereby **ORDERED** that the plaintiffs' Motion to Compel (ECF No. 279) is granted. The court finds that the plaintiffs attempted in good faith to obtain the discovery without court action. Pursuant to Rule 37(a)(5), and based on AMS's response, the court finds that AMS's position is not substantially justified. The plaintiffs may file an affidavit of their reasonable expenses incurred in making the motion, including attorney's fees, within one week of the filing of this Order. AMS shall file its response within one week of the filing of the affidavit, advising whether AMS or its counsel or both will pay the plaintiffs' reasonable expenses.

The court **DIRECTS** the Clerk to file a copy of this Pretrial Order # 24 in 2:12-md-2325, and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:12-cv-06456. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: October 30, 2012

Mary E. Stanley
United States Magistrate Judge